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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Hideo Kawachi

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EXAMINER

WEBB, WALTER E

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

10/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,682	Applicant(s) KAWACHI, HIDEO	
	Examiner WALTER E. WEBB	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/2/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/2/2009 has been entered.

Applicants' arguments, filed 9/2/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112--New

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "trace amount" in claim 1 is a relative term which renders the claim indefinite. The term "trace amount" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in

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the art would not be reasonably apprised of the scope of the invention. It is not clear how small the amount of water can be and qualify as being useful in a method of separating ergosterol from a solution in water-insoluble organic solvent. The term "such a range of amount that no phase separation occurs between the water-insoluble organic solvent" renders the claims indefinite for the same reasons. This term is defined as "a trace amount of water that can be dissolved in a water insoluble organic solvent " (see pg. 7, 1st paragraph). This definition assumes that there is only **one** amount that suffices **for each** water insoluble organic solvent. The artisan would reasonably expect a range as per the example given in the specification, i.e. "approximately 1 to 100 ppm with respect to hexane" (see Id.).

Claim Rejections - 35 USC § 102

1) Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Bills (US 1,775,548).

Bills teaches a method of purifying ergosterol. The purifying process demonstrated crystallized product of ergosterol, which amounted to 60% of the original crude ergosterol. (See col. 2, lines 85-97.)

2) Claim 7 remains rejected under 35 U.S.C. 102(b) as being anticipated by Knol (US 2,536,753).

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Knol teaches a method of recovering and purification of sterols. (See col. 1, lines 1-3.) Ergosterol is dissolved in iso-octate; water is added yielding 90% ergosterol precipitate. (See col. 7, lines 29-37.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

New

1) Claims 1, 3, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bills (US 1,842,929), which relies on (US 1,775,548).

Bills teaches a method of preparing ergosterol, where ergosterol is extracted from saponification of yeast fat. (See col. 1, lines 37-40, and col. 2, lines 65-92.) The yeast fat, being fat, comprises **aliphatic hydrocarbons**. Water is added to the saponification mixture to precipitate ergosterol. (See *ibid.*) The water was added to such an extent as not to incomplete precipitation. (See col. 2, lines 78-87.) The purification process was set forth in application serial number 355,440 also US Patent 1,775,548. (See col. 3, lines 15-20.) The purifying process from that reference demonstrated a crystallized product of ergosterol, which amounted to 60% of the original crude ergosterol. (See col. 2, lines 85-97 of US Patent 1,775,548.)

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Bills does not teach that the amount of water supplied is within a range such that no phase separation occurs between the water insoluble organic solvent and water. However, the instant specification and Bills are both concerned with adjustment of the water added for producing a good yield of ergosterol. The instant specification states that if the amount of water is too large the solution becomes difficult to handle (see instant specification at pg. 7, lines 2nd paragraph). Bills teaches that if the amount of water is too large the separation becomes "unnecessarily difficult" (see 2nd column, lines 83-87). Furthermore, the yield of the crystallized product of ergosterol taught in Bills, 60%, falls within the range of ergosterol crystallinity, as an aggregate, instantly claimed, 50% to 90%. Thus, it appears that the amount of water disclosed in Bills reads on the method of the instant claim 1.

2) Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bills (*supra*) as applied to claims 1, 3, 6 and 7 above, in view of Nimberger et al., (US 5,498,138).

Bills, differs from the instant claim 5 insofar as it does not teach wherein the water supply is conducted by continuously or intermittently moisturizing a gas phase portion within an apparatus for precipitating ergosterol.

Nimberger et al. teaches a fluid regulator for adjusting fluid sprayed in an apparatus (see abstract).

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to supply water as in claim 5, motivated by the teaching of Bills

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that correct amount of water is important for precipitation. Claim 5 reads on supplying water through a fluid regulator, which monitors the amount of water administered. See Nimberger et al. at abstract for example of fluid regulator. It would have been obvious to use the fluid regulator to ensure that the right amount of water is used for the precipitation of ergosterol from the organic solution of Knol. Such a device would be useful in an apparatus for mass production of ergosterol.

Previous

3) Claims 1, 3 and 6-8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Knol (US 2,536,753) in view of Bills (*supra*).

Knol teaches a method of recovering and purification of sterols. (See col. 1, lines 1-3.) Ergosterol is dissolved in iso-octane (**aliphatic** water insoluble organic solvent); water is added yielding 90% ergosterol precipitate. (See col. 7, lines 29-37.) The reference teaches that ergosterol may also be isolated from yeast via the same process, as per claim 3. (See col. 9, lines 1-8.) In regard to claim 8, Knol teaches ergosterol precipitation by a cooling crystallization insofar as it teaches a cooling step in the process to generate the ergosterol (see col. 7, lines 29-37).

Knol differs from the instant claim 1 insofar as it does not teach supplying a trace amount of water such that no phase separation is formed between the water-insoluble organic solvent and water.

Bills teaches that too much water will hold the ergosterol partly in colloidal suspension, while too little water will cause incomplete precipitation. (See *ibid.*)

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It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to adjust the water such that no phase separation occurs, motivated by the teaching of Bills that success of precipitation of ergosterol depends on the correct amount of water (see col. 2, lines 78-87.)

4) Claim 5 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Knol (*supra*) and Bills (*supra*), and in further view of Nimberger et al., (US 5,498,138).

The combination of Knol and Bills, differs from the instant claim 5 insofar as it does not teach wherein the water supply is conducted by continuously or intermittently moisturizing a gas phase portion within an apparatus for precipitating ergosterol.

Nimberger et al. teaches a fluid regulator for adjusting fluid sprayed in an apparatus (see abstract).

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to supply water as in claim 5, motivated by the teaching of Bills that correct amount of water is important for precipitation. Claim 5 reads on supplying water through a fluid regulator, which monitors the amount of water administered. See Nimberger et al. at abstract for example of fluid regulator. It would have been obvious to use the fluid regulator to ensure that the right amount of water is used for the precipitation of ergosterol from the organic solution of Knol. Such a device would be useful in an apparatus for mass production of ergosterol.

New

5) Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knol (supra) and Bills (supra) as applied to claims 1, 3 and 6-8 above, and further in view of Watannabe et al., (US 4,447,362).

The combination of Knol and Bills differs from the instant claim 4 insofar as they do not teach where the organic solvent is hexane, heptane, octane, or a mixture thereof.

Watannabe et al. teaches the use of hexane and isooctane as water insoluble organic solvents for extraction purposes (see col. 2, lines 48-50).

Generally, it is obvious to replace one component for another equivalent component if it is recognized in the art that two components are equivalent and is not based on the Applicant's disclosure (see MPEP 2144.06).

Thus it would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to use hexane as the organic solvent in the process of Knol based on the prior art's recognition that such species are equivalent, as evidenced by Watannabe et al.

Response to Arguments

Applicant argues that the amount of water taught in the method of Bills, 1 liter, added to the amount of organic solvent described in Knol would result in two phases. However, Bills was **not** used as providing motivation for using water in the composition of Knol, but provided motivation for adjusting the amount water in the method of Knol. Bills taught that water is a result effective variable, and that it is critical that the amount of water used was just right for the purposes of precipitating ergosterol. In the method if

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Bills, 1 liter sufficed to be effective for the precipitation. In the method of Knol, where a different solvent is used, the amount of water would be different. The difference would be based on the result, as evidenced by Bills, i.e. a complete precipitation.

Claim Objections—Allowable Subject Matter

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

A search of the prior art did not reveal a teaching for a method of separating ergosterol, or sterols generally, from a hexane solvent where water is supplied within a range of 1 and 100 ppm. The closest prior art, discussed above, teaches the use of hexane, among others, as a solvent for ergosterol but does not teach the specific range of water to be supplied in the extraction. Applicant also discloses that the amount of water supplied depends on the type of solvent used, and 1 and 100ppm was determined to be the useful range of water supplied in regard to hexane (see pg. 7, bottom of first paragraph).

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612